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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/901,938	07/10/2001	Michael Econs	053884-5001	9281

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EXAMINER

SAOUD, CHRISTINE J

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 07/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/901,938	Applicant(s) ECONS ET AL.	
	Examiner Christine J. Saoud	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-83 is/are pending in the application.
- 4a) Of the above claim(s) 17-31, 34, 35, 39-42 and 44-83 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 14-16, 32, 33 and 43 is/are rejected.
- 7) ☒ Claim(s) 13 and 36-38 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Upon further consideration and in response to Applicant's phone call on 16 June 2004, Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Since Applicant's arguments were answered in the previous Office action, the response to the previously presented arguments will not be repeated. However, all outstanding grounds of rejection and issues are as follows.

Claim Amendments

Claim 31 is improperly notated. While this claim is indeed an original claim, it is withdrawn, and should be noted as such.

Claim Objections

Claims 36-38, in so far as they encompass non-elected subject matter (i.e. FGF-23 molecules not related to SEQ ID NO:1) are objected to. Furthermore, these claims depend from non-elected claims, and therefore, are objected to. Since these claims are directed to non-elected subject matter and depend from non-elected claims, they should either be canceled or amended.

Claim Rejections - 35 USC § 112

Claims 1-12, 14-16, 32-33 and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "comprising SEQ ID NO:1", however, it is not clear if the nucleic acid comprises SEQ ID NO:1 or if the fibroblast growth factor-23 comprises SEQ ID NO:1. Use of the transitional phrase "wherein said comprises SEQ ID NO:1" may obviate this ground of rejection.

Claims 1-4 and 43 recite "has/having the biological activity of FGF23". However, upon reading the instant specification, the term "FGF23" is intended to encompass molecules of different structure (variants, mutants, homologs, % identity similarity, etc.), and therefore, different activities. Therefore, there is insufficient antecedent basis for "the biological activity of FGF23" since a fair reading of the specification would indicate that "FGF23" has more than one activity. Applicant may wish to amend the claims to include a biological activity so that the metes and bounds of the claims can be determined. Claims 5-11 and 32 are indefinite for depending from indefinite claims.

Claim 12 recites "fibroblast growth factor-23 (FGF23)" with no associated structure, and the metes and bounds of what this term encompasses are not clear. The art acknowledges that many proteins may go by different names as well as some names which can signify many different proteins. Therefore, the mere recitation of a name with no associated structure places no material limitations on what is being claimed. In the art of fibroblast growth factors, the newest member is given the next

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highest number preceded by FGF. However, as in any art, there are new protein members being discovered daily, therefore, Applicant's "FGF23" may be someone else's "FGF25". Therefore the instant claim is indefinite.

Claims 14-16 and 33 are indefinite because they depend from an indefinite claim, claim 12.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 3-4, 12, and 33 rejected under 35 U.S.C. 102(e) as being anticipated by either US 2002/0082205 A1 (Itoh et al.) or US 2002/0102604 A1 (Milne Edwards et al.).

Itoh et al. teach a protein which is encoded by a nucleic acid. The protein is 100% identical to the protein of the instant application. The effective filing date of Itoh et al. is 08 March 2000, which is prior to Applicant's effective filing date of 19 July 2000, making the reference prior art under 102(e). See Itoh et al.'s SEQ ID NO:4 (protein) and SEQ ID NO:3(nucleic acid). Itoh et al. also disclose compositions comprising the nucleic acid beginning at paragraph [0093].

Milne Edwards et al. teach a nucleic acid molecule (SEQ ID NO :57) which encodes a protein (SEQ ID NO :298) which is 100% identical to the protein of the instant application. The nucleic acid molecule of Milne Edwards et al. is shorter than the nucleic acid molecule of SEQ ID NO:1 of the instant application, but is 99.9% identical over a stretch of 1240 bases, which includes the protein coding region. The effective filing date of Milne Edwards et al. is 08 December 1999, which is prior to Applicant's effective filing date of 19 July 2000, making the reference prior art under 102(e). Milne Edwards et al. additionally disclose compositions comprising the nucleic acid and an acceptable carrier (see at least paragraph [0540]). Therefore, the instant claims are anticipated by the prior art.

Allowable Subject Matter

Claim 13 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 571-272-0891. The examiner can normally be reached on mttr, 8:00-2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CHRISTINE J. SAOUD
PRIMARY EXAMINER

A handwritten signature in black ink that reads "Christine J. Saoud". The signature is written in a cursive style with a large, stylized "C" and "S".